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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,431	02/27/2004	Daniel Cohn	7640-X04-018	5690
27317 7590 03/26/2008 FLETT KAIN GIBBONS GUTMAN BONGINI & BIANCO 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180				
EXAMINER MAHYERA, TRISTAN J				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
03/26/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/789,431

**Applicant(s)**

COHN ET AL.

**Examiner**

TRISTAN J. MAHYERA

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 9 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-27 are pending. Claims 1-27 are examined on the merits.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a-d) as follows:

In order to receive the benefit of the earlier foreign filing date applicant must supply a certified copy of ISRAEL 151288 filed on 8/15/2002.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filled application, Application No. 60/314,640, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Instant claims 1, 13 and 15 comprise two "environmentally" responsive polymeric components. Instant claims 1, 6, 7, 8, 26 and 27 state insertion into the "human" body. No support for "environmentally" or "human" is found in the priority document. Instant claim 10 recites "diversity of spatial arrays are obtained, dispersed homogeneously or heterogeneously, isotropically or anisotropically within the system, generating macro, micro or nanoscopic independent or interconnected domains within the system.", however, no support for this description of the solid component is found in the priority document. Instant claim 11 recites "random" or "alternating" reverse thermo-responsive PEO-PPO block copolymers, however no support is found in the priority document. Instant claim 12 recites "a poly(alkyl-co-oxyalkylene) copolymer having the formula  $R-(OCH_2CH)_n-OH$ , where R is an hydrophobic monofunctional segment selected from a group consisting of poly(tetramethylene glycol), poly(caprolactone), poly(lactic acid), poly(siloxane) and combinations thereof, a poly(alkyl-co-oxyalkylene) copolymer having the formula  $[-R'-(OCH_2CH)_n-O]_pH$ , where R' is a bifunctional or multifunctional hydrophobic segment, a poly(N-alkyl substituted acrylamide)s, cellulose and cellulose derivatives and combinations thereof." No support is found for the limitation of instant claim 12 in the priority document. Instant claim 14 recites "ultrasound" radiation, of which only support for radiation is found, not for ultrasound. Instant claims 15 and 20 state the components contain "organic" or "inorganic" materials, however no support for such components is

found. Instant claim 22 states the responsive component contains components of biological origin selected from a group consisting of "elastin, a collagenous material, albumin, a fibrinous material, demineralized tissue or an acellular tissue matrix and combinations thereof.", however no support for this group is found. Instant claim 24 recites "ex vivo as well as *in vivo*", yet no support is in the priority document. Instant claims 15 and 27 state "non-responsive", however no support for such a group is found in the priority document.

Therefore, in light of the above referenced claim limitations, the priority date is set at 8/22/2002.

### ***Specification***

The disclosure is objected to because of the following informalities: p[00075] and p[00076] should be connected as one paragraph. The specification contains what appears to be references to the International Search Report, for example, "(D3)" in p[00079] and "(D4)" in p[00081]. These identifiers have no meaning within the instant disclosure and must be removed. Applicant's assistance is requested in finding additional occurrences of these identifiers.

The use of the trademarks PLURONIC, TETRONIC and JEFFAMINE (p[00050]) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

### ***Claim Objections***

Claims 9 and 26 are objected to because of the following informalities: There are two (2) claims numbered 26. Claim 9 line 3 contains "vrious"; it should be "various".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim 1 recites "polymer components capable of undergoing a transition that results in a sharp increase in viscosity in response to a change in temperature at a predetermined body site", however the disclosure does not teach all the polymeric components capable of undergoing such a sharp change in viscosity. Furthermore, no guidance is given on how to determine which polymers components would undergo such a transition. Instant claim 10 recites a

"diversity of spatial arrays are obtained, dispersed homogeneously or heterogeneously, isotropically or anisotropically within the system, generating macro, micro or nanoscopic independent or interconnected domains within the system", however the specification does not reasonably convey how to engineer solid components in the system having a diversity of spatial arrays. Instant claim 14 recites "ultrasound radiation", however the specification is silent on which polymer compounds are affected by "ultrasound" when used as a stimuli and the effect on the polymer from ultrasound. Instant claim 27 recites that the "non-responsive material polymerizes and/or crosslinks", however no description exists that explains how a "non-responsive" material is actually crosslinking or polymerizing upon insertion into a body. Furthermore, in both claims 15 and 27 there is no guidance to determine what structures are "non-responsive".

Claims 2-9, 11-13 and 16-26 are rejected as depending from rejected claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 10, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "sharp" in claims 1 and 3 is a relative term which renders the claim indefinite. The term "sharp" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the

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scope of the invention. A "sharp" increase in viscosity in response to a change in temperature does not set forth in a distinct manner the actual increase in viscosity the Applicant is trying to convey. Neither does the term convey any particular rate of time for such increase in viscosity. Claim 10 recites the limitation "said solid components" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 is narrative and indefinite, failing to conform with current U.S. practice. It appears to be a literal translation into English from a foreign document. Claims 23 and 24 are interpreted as merely the intended use of the polymeric system without any structural components to determine the metes and bounds of the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-9, 13, 15, 19, 20, 23, 25(first of the claims numbered 26), and 27 are rejected under 35 U.S.C. 102(a & e) as being anticipated by PIAO et al. (WO 01/82970 see PTO-892).



PIAO teaches a water soluble biodegradable reverse thermal gelation system comprising a mixture of at least two types of tri-block copolymer components. The two or more triblock copolymers of PIAO consist of biodegradable polyester and polyethylene glycol (PEG) blocks. See e.g. page 1 lines 1-10; instant claims 1 and 3. The two triblocks have different thermal gelation properties. See e.g. page 20 lines 26-27 in Example 7; instant claim 1. The viscosity changes when heated. See e.g. page 6 line 30 to page 7 line 10; instant claims 2 and 3. The components are in an aqueous solution. See e.g. claim 14; instant claims 6 and 7. A component of the system can be in the solid or gel state at insertion. See e.g. page 14 lines 7-8; instant claim 8. Claim 9 does not add any new structural limitations, referring only to how the polymeric component can be adapted to different morphological forms, and since polymeric compounds, specifically those of PIAO can adapt to any shape or form the claim is anticipated. The reference teaches the polymeric components can be different. See e.g. page 3 lines 10-12 and Example 7 lines 26-27; instant claim 13. The system comprises drugs with biological roles, specifically polypeptides and proteins, genes, hormones and anti-cell proliferation agents. See e.g. claims 14 and 17; instant claims 14, 15, 19 and 20. Claim 23 is interpreted as having no additional structural limitations from claim 1 and because PIAO teaches within the art of implants for post-surgical adhesions/tissue engineering, PIAO anticipates claim 23. The "displaying initially a defined interface" in Claim 25(i.e. the first claim numbered 26) is interpreted as occurring whenever two or more polymeric compounds are in contact, whether as a mixture or other morphological form. See e.g. Claims 1 and 2; instant claim 25.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 10-12, 14, 16-18, 21, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over PIAO in view of COHN et al. (US 2003/0082235 see PTO-892).

PIAO teaches a water soluble biodegradable reverse thermal gelation system comprising a mixture of at least two types of tri-block copolymer components, as described above. PIAO further teaches that the two copolymers can be the same. See e.g. Table 1, page 10; instant claim 5.

PIAO does not explicitly teach PEO-PPO-PEO triblocks, polymeric components that are crosslinked or the use of living cells or elastin.

COHN teaches reverse thermo-responsive polymeric systems comprising environmentally responsive components in an aqueous solution which undergoes a change in viscosity. The responsive component is a segmented block copolymer comprising PEO and PPO chains, wherein the PEO and PPO are connected via a chain extender. See e.g. p[0049] and Example 1; instant claims 11 and 12. The polymer is crosslinked. See e.g. p[0057], p[0016] and p[0006]; instant claims 16-18. The components can be of biological origin, specifically elastin, collagenous material, albumin, demineralized tissue, a cellular tissue matrix and combinations thereof. See e.g. claim 25; instant claim 22. The reference teaches the use of living cells in the system. See e.g. claim 22; instant claim 21 and 24. The different polymeric compositions are engineered to display different degradation kinetics, designed to cover a broad range of mechanical properties. See e.g. p[0053] and p[0014]; instant claim 10. The prior art describes the use of responsive polymer networks exhibiting reverse

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gelation triggered by pH and ionic strength for use in tissue engineering and drug delivery. See e.g. p[0006]; instant claim 14.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition comprising two derived responsive polymeric components in particular triblocks derived from PEG and PPO with poly ester chains that display different gelation behavior, as taught by PIAO in view of COHN. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because the polymeric components are non-toxic and suitable for tissue engineering, as taught by COHN. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/  
Examiner, Art Unit 1615

/Michael P Woodward/  
Supervisory Patent Examiner, Art Unit 1615